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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,637	05/04/2001	Dov Malonek	20066.79	6911

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	13

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/849,637	MALONEK ET AL.
	Examiner	Art Unit
	George R Evanisko	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-33 and 35-67* is/are pending in the application.

4a) Of the above claim(s) *33,46-48 and 50-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-32,35-45 and 62-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 33, 46-48, and 50-61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-33, 35-40, 49, and 62-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 12 and 19, "or any other conductive material having suitable...characteristic" is vague since the claims or specification do not specifically point out what constitutes a "suitable" biostable and biocompatible characteristic.

In claim 25, "means of" is vague and "connected by...means of crimping" is inferentially included.

In claims 38 and 39, "may be" and "may be identified by using" are vague since it is unclear if applicant is trying to claim a method step or an element to perform those functions. In addition, it can not be determined if the element has that function since "may be" could mean it has that function or it doesn't have that function.

Claim 49 is vague and is not limiting independent claim 62. The claim does not contain any further structural limitations and is claiming how the lead is implanted using any suitable implantation method.

In claim 62, "may comprise..." is vague since it can not be determined if the element/function is being positively recited. The element "may" be a unitary electrode and it "may" not be a unitary electrode.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In each of the references used for the rejections below, the references provide some sort of means for suitable control (the claimed "suitable control means" has only been given a function of means for suitable control) since the leads and electrodes deliver a pulse or no pulse from a connected implantable pulse generator.

Claims 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Pless et al (5456706). Pless is capable of meeting the functional use recitations presented in the claims.

Claims 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffmann et al (5534022). Hoffmann is capable of meeting the functional use recitations presented in the claims.

Claims 11, 28, 35-45, 49, and 62 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kieval (5814079).

Claims 11, 35-45, 49, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Noren et al (5649966). It is inherent that Noren contain some type of connection means for connecting the electrodes to the control means. Such connection being a connector, a conductor, and/or the lead itself. In addition, Noren is capable of performing the functional use recitations presented in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 35-45, 49, and 62 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scherlag (5083564).

Scherlag uses conventional leads with an electrode separation being one mm to ten mm. In addition, Scherlag states that the system can be incorporated into an implantable system with sensing and delivering of the pulses and will inherently have a control means to control the

stimulation. In addition, Scherlag inherently contains connection means to connect the electrodes to the control means. Such connection being a connector, a conductor, and/or the lead itself. In addition, Scherlag is capable of performing the functional use recitations presented in the claims.

In the alternative, Scherlag discloses the claimed invention except for the control means to receive the signals and determine the parameters of the electric field and deliver the field to the electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable stimulator as taught by Scherlag, with the control means to receive the signals and determine the parameters of the electric field and deliver the field to the electrodes since it was known in the art that implantable devices use a control means to receive the signals and determine the parameters of the electric field and deliver the field to the electrodes to provide an automated system that controls the device to sense heart signals, determine electric pulse parameters, and deliver the pulses to the electrodes that does not require constant intervention from a physician.

Claims 5-10, 12-32, and 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noren (or Scherlag or Kieval).

Noren (or Scherlag or Kieval) discloses the claimed invention except for the specifics of the lead/electrodes, such as the lead being a single lead having 2 pairs of electrodes, minimizing the distance between electrodes being about 5 mm, the sensing electrode having a lumen diameter larger than a distal portion of the lead and longitudinal length less that the external diameter (less than 1.2 mm), the electrode materials having suitable biostable and biocompatible

characteristics, a delivery electrode wound in parallel to a spiral coil-like form having an external diameter larger than a distal diameter, the spiral coil form having a longitudinal length, 20 mm, substantially greater than the external diameter and an effective surface area of about 30-250 square mm, electrodes spaced to occupy 20-150 mm, conductors and suitable connectors for each electrode, an IS1 connector, ogival intrusion head and a length of suitable tubing with a bend at about 45 degrees, means to introduce the lead, and a diameter to allow the lead to pass through a lumen of less than about 1.5 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead and electrodes as taught by Noren (or Scherlag or Kieval), with the specifics of the lead/electrodes recited above, since it was known in the art that leads/electrodes incorporate the specifics of the lead/electrodes recited above, to provide implantable, biocompatible leads and electrodes that can be easily placed and maintained in the heart to deliver electrical therapy to the heart and sense electrical signals from the heart.

Noren (or Scherlag or Kieval) discloses the claimed invention except for the diameter being less than 1.2 mm or the electrode impedance being between 50 and 500 Ohms (claims 14 and 18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead having electrodes as taught by Noren (or Scherlag or Kieval), with the lead diameter being less than 1.2 mm and the electrode impedance being between 50 and 500 Ohms since it was known in the art that leads having electrodes use a lead diameter less than 1.2 mm to allow the lead to have a small footprint in the body and/or to allow the lead to be placed in the coronary veins and since it was known in the art that leads having

electrodes provide the electrode with an impedance between about 50 to about 500 Ohms to provide a low impedance lead that will not waste energy of the implantable device.

Noren (or Scherlag or Kieval) discloses the claimed invention except for the multiple lumens each having a conductor (claim 22), the particulars of the distal connector means comprising a substantially flat terminal member (claim 23), connecting the conductors to the distal connector using laser welding or crimping (claims 24 and 25), the terminal member being titanium (claim 26), and spiraling of the conductors in the lead lumen (claim 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead having electrodes as taught Noren (or Scherlag or Kieval), with the lead having multiple lumens with each lumen having a conductor, connection of the conductors to distal connectors using laser welding or crimping, and the spiral conductors in the lumens since it was known in the art that leads having electrodes use: multiple lumens, with each lumen having a conductor in the lumen to allow the lead body to have a smaller footprint in the body by not using insulation on each conductor; laser welding or crimping to connect conductors to distal connectors to provide a fast, secure method for the connection of different elements; and to spiral the conductor in the lumen to allow the lead to be more flexible and less resistant to breakage.

In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead having electrodes as taught by Noren (or Scherlag or Kieval) with the particulars of the distal connector means comprising a flat terminal member and the terminal member being titanium, because Applicant has not disclosed that the particulars of the distal connector means comprising a flat terminal member and the terminal member being titanium provides an advantage, is used for a particular purpose, or solves a stated problem. One

of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the connections of the conductors to the connectors as taught by Noren (or Scherlag or Kieval), because it provides a secure connection of the conductors to the connectors and allows sensing or applying a field to take place.

Therefore, it would have been an obvious matter of design choice to modify Noren (or Scherlag or Kieval) to obtain the invention as specified in the claim(s).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The argument that the electrode systems of the prior art can not be used to apply a localized signal is not persuasive since the claims do not contain any limitations to applying a localized signal but only that the electrodes be "either" unitary or in close proximity. In addition, the range or extent of the localized signal or proximity has not been specifically defined except in those claims where the distance between the electrodes are recited. The argument that the large surface area of the electrodes mean that a high enough current density cannot be attained to produce non-excitatory signals for a protracted period of time without depleting the energy source of the device is not persuasive since the amount of time the device operates has not been claimed.

The prior art used in the rejections above show multiple different leads and electrodes being used to deliver non-excitatory stimulus pulses. The electrodes ranging from large surface area defibrillation electrodes to pacing and sensing electrodes from conventional implantable leads. In addition, the prior art cited in the last detailed action show the details that are well known in the art for the 103 rejections related to the specifics of the lead and electrodes. It is

suggested to incorporate most, if not all, of the specifics of the lead and electrodes into claims that also contain control means to deliver the non-excitatory pulses. Although, those claims will need to be further searched and examined.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762

2/22/4

GRE
February 22, 2004